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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,027	12/05/2003	Xin-Xing Gu	NIH142.1CDV1	8829
45311	7590	03/08/2006	EXAMINER	
KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/729,027	Applicant(s) GU ET AL	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/2005</u> | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed November 14, 2005. Claim 23 has been amended. Claims 1-22 and 29-38 have been cancelled.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

3. In view of Applicant's amendment the rejection of claims 23-28 under 35 U. S.C. 112, first paragraph, pages 2-6, paragraph 4 of the previous Office action is withdrawn.

New Grounds of Rejection Necessitated by Amendment

Claims Objection

4. Claim 23 is objected for the following informality: "*M. catarrhalis*" should be changed to "*Moraxella catarrhalis*" because the proper name of an organism should be used at the first occurrence in the claims.

It should be noted that the Examiner is viewing *Branhamella catarrhalis* and *Moraxella catarrhalis* to be the same microorganism since the instant specification on page 1 teaches that they are the same microorganism.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 23-28 are rejected under 35 U.S.C. 103(a) as unpatentable over Gu et al (*Infection and Immunity*, October 1996, p. 4057-4053) in view Campagnari et al (*Microbial Pathogenesis*, 1990, Vol. 8, No. 5, p. 353-362).

Claims 23-28 are drawn to a method of making an immunogenic composition comprising removing ester-linked fatty acids from lipooligosaccharide (LOS) isolated from *M. catarrhalis* to produce detoxified LOS (dLOS) and covalently linking the dLOS to an immunogenic carrier.

Gu et al teach a method of making an immunogenic composition comprising lipooligosaccharide (LOS) from a gram-negative microorganism (*Haemophilus influenzae*). Gu et al teach that LOS was detoxified to remove the esterified fatty acids using hydrazine treatment (page 4048). Gu et al teach that the LOS from the gram-negative organism was conjugated to a protein carrier (tetanus toxoid) by a linker

compound (adipic acid dihydrazide) (page 4048). Gu et al teach that an adjuvant (Ribi-700) was added to the LOS-conjugates and mice were immunized with the composition.

Gu et al do not teach lipooligosaccharide (LOS) isolated from *M. catarrhalis*.

Campagnari et al teach lipooligosaccharide isolated from *Moraxella catarrhalis* (*Branhamella catarrhalis*) (see the Abstract). Campagnari et al teach that non-enteric gram-negative human pathogens *Branhamella catarrhalis*, and *Haemophilus influenzae* do not have repeating O-antigens as part of their principle surface glycolipid, (the lipooligosaccharide) (LOS)(see the Abstract). Campagnari et al teach that the structure of *Branhamella catarrhalis*, and *Haemophilus influenzae* are similar and have conservative epitopes among them (see the Abstract). Campagnari et al suggest that these conservative epitopes among the gram-negative pathogens are important in the ability of specific organisms to elude host defenses and initiate infection (page 360).

It would be *prima facie* obvious at the time the invention was made to employ the method of Gu et al in making an immunogenic composition from *Moraxella catarrhalis* because Campagnari et al disclose *Haemophilus influenzae* (i.e. *Branhamella catarrhalis*) have similar structures in terms of the lipooligosaccharides (LOS). It would be expected, barring evidence to the contrary, that the method of Gu et al would be effective in making an immunogenic composition from *Moraxella catarrhalis*.

Status of Claims

6. No claims allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
February 20, 2006


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